C-Path Quantitative Medicine Program Awarded FDA Contract to Develop Tools for Neuroscience Diseases

TUCSON, Ariz., December 2, 2020 — The Critical Path Institute (C-Path) today announced it has been awarded a U.S. Food and Drug Administration (FDA) contract in support of the development of open-source tools to improve the efficiency of trial design for three neuroscience diseases: Alzheimer's disease (AD), Parkinson's disease (PD) and Duchenne muscular dystrophy (DMD). C-Path's Quantitative Medicine (QuantMed) Program will carry out the project through its work in collaboration with its three C-Path Public-Private Partnerships: the Critical Path for Alzheimer's Disease (CPAD), the Critical Path for Parkinson's (CPP) and the Duchenne Regulatory Science Consortium (D-RSC).

Under the contract, the objective is to provide quantitative solutions to address unmet needs in AD, PD and DMD. The analyses are intended to evaluate standard clinical trial designs and provide recommendations with respect to endpoints and trial populations.

"The quantitative solutions developed will focus on practical and robust tools for sponsors to optimize clinical trial design," said Executive Director of Quantitative Medicine Jackson Burton, Ph.D. "An important step is to leverage the strong industry representation in CPAD, CPP, D-RSC, as well as the FDA, to identify key drug development questions. Such questions will inform what types of solutions C-Path's QuantMed Program team will work to develop."

Patient-level data that have been acquired by CPAD, CPP and D-RSC, thanks to industry data sharing initiatives, will be used to inform the development of the tools. The acquired data have been curated, standardized and integrated within the respective CPAD, CPP and D-RSC databases.

"Our expertise in developing tools to improve trial design continues to expand and we're honored FDA chose C-Path to carry out this initiative," said C-Path Chief Science Officer Klaus Romero, M.D., M.S., F.C.P. "The insights generated from these tools are intended to be disseminated to the broader drug development community through several platforms."

For more information on QuantMed's current regulatory endorsed tools, visit: c-path.org/programs/quantmed .

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Critical Path Institute (C-Path)) is an independent, nonprofit organization established in 2005 as a public and private partnership. C-Path's mission is to catalyze the development of new approaches that advance medical innovation and regulatory science, accelerating the path to a healthier world. An international leader in forming collaborations, C-Path has established numerous global consortia that currently include more than 1,600 scientists from government and regulatory agencies, academia, patient organizations, disease foundations, and dozens of pharmaceutical and biotech companies. C-Path US is headquartered in Tucson, Arizona and C-Path, Ltd. EU is headquartered in Dublin, Ireland, with additional staff in multiple other locations. For more information, visit www.c-path.org and c-path.eu.

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